

REMARKS/ARGUMENTS

In this Amendment, claims 35, 36, 38, 39 and 55 are currently amended. Claims 1-33, 37, 49, 51, 53 and 54 are canceled without prejudice or disclaimer; claims 34, 40-42, 45-48, 50, 52 and 56-67 were previously presented; and claims 43 and 44 stand withdrawn. No new matter has been introduced into the application by virtue of the amended claims.

The amendments to claims 35, 36, 38, 39 and 55 are fully supported by the instant specification. Support for the energy input procedure for reduction of particle size selected from one or more of sonication, milling, homogenization, microfluidization, or precipitation from solution using antisolvent and solvent precipitation, in the presence of the mixture formed in step (1) of these claims, is found on page 7, lines 1-5 of paragraph 3. Example 1, page 8, lines 6-18 of the specification provides further support for the amended claims.

Accordingly, claims 34-36, 38-42, 45-48, 50, 52 and 55-67 are currently pending in this application.

As mentioned in Applicant's previous response, it is respectfully requested that upon a determination of allowability of the currently pending claims, including the elected species, in this application, the Examiner extend examination to the non-elected species of claims 43 and 44 that read on the pending claims, as mentioned on page 3 of the 10/01/03 Office Action (Paper No. 26).

The currently amended claims satisfy 35 U.S.C. §112, second paragraph

Claims 34-36, 48-48, 50, 52 and 55-67 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. According to the Examiner, the preamble of independent claims 35, 36 and 38 is confusing as steps (1) and (2) of the method do not indicate in which step the recited processes are utilized. Applicants respectfully submit that the currently amended claims clearly recite the step of the method in which the size reducing procedures are utilized in the claimed methods. In view of the currently amended claims, this rejection is mooted. Accordingly, it is respectfully requested that the rejection under 35 U.S.C. §112, second paragraph, be withdrawn.

Obviousness-Type Double Patenting Rejections

Claims 34-36, 38-48, 50, 52 and 55-67 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1, 2, 4-25, 45-47, 52, 53, 55, 56, 65, 101-104 and 109-119 of copending application U.S. Serial No. 10/260,788.

According to the Examiner, the conflicting claims are not identical, but are not considered to be patentably distinct from each other because the “claims in both applications are drawn to the same method of preparing microparticles.”

To expedite prosecution of the application without acquiescing to the propriety of this rejection, a terminal disclaimer and the required fee are submitted herewith. Withdrawal of the rejection is thus respectfully requested.

Claims 34-36, 38-48, 50, 52 and 55-67 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 45-97 of copending application U.S. Serial No. 10/443,772 (hereinafter “the ‘772 application”).

According to the Examiner, the conflicting claims are not identical, but are not considered to be patentably distinct from each other because the “claims in both applications are drawn to the same method of preparing the microparticles of fenofibrate.”

Applicants respectfully disagree with this rejection. First, the claims of the ‘772 application are not directed to a method of making fenofibrate microparticles, but rather are directed to a process of preparing a rapidly disintegrating solid dosage form comprising stabilized fenofibrate microparticles. The process claimed in the ‘772 application requires components and steps that function as particularly described in the claims to produce the rapidly disintegrating solid dosage form. The claimed invention as supported by the teaching of the ‘772 application is distinct from and distinguished over the instant claims. The instant claims are plainly different from the ‘772

application's claims, which recite the use of rapidly dispersible matrix-forming bulking and releasing agents, or combinations thereof, in amounts that allow for the functions of the rapidly disintegrating dosage form.

The instant claims are not drawn to and are not obvious over the claimed process of the '772 application. The claims of the '772 application are drawn to admixing a homogeneous aqueous suspension of microparticles comprising fenofibrate and surface stabilizing agents, including at least one phospholipid, and one or more rapidly dispersible matrix forming bulking and/or releasing agents to produce a dried solid form of the suspension having the recited properties of non-aggregation and non-agglomeration, and further producing a solid that has stabilized drug particles dispersed and embedded throughout a support matrix formed by the one or more bulking and/or releasing agents, such that this support matrix disperses with a rapid disintegration time. The instant claims do not require a solid support matrix in which drug (i.e., fenofibrate) particles are dispersed and embedded throughout. The steps, components and functionalities as claimed in the '772 application are distinct from the instantly claimed invention. The '772 application's claims clearly describe a process that involves steps, components and functional results that are distinctive and unobvious in view of the methods claimed in the instant application.

Second, the claims as a whole must be considered in making a determination of obviousness. In view of this, it is submitted that the claims of the '772 application, considered as a whole, contain steps that are patentably distinguished over the presently amended claims considered in their entirety. Based on the teachings of the applications, Applicants respectfully assert that it would not have been obvious for one having skill in the art to arrive at and utilize the particular "additional steps" recited in the claims of the '772 application, which contain particular components and functions for producing a rapidly disintegrating fenofibrate microparticle dosage form, to arrive at the presently claimed invention considered as a whole. The inventions claimed in the instant application and in the '772 application are patentably distinct and are not obvious in view of each other.

Lastly, it is impermissible to invoke hindsight reconstruction to determine that the instantly claimed method is made obvious by the claims of the '772 application, which are drawn to a distinctly different process comprising similar, but also additional and distinguishing steps and components that function together in a nonobvious manner to achieve a nonobvious result as recited in the claims of the '772 application. It is respectfully submitted that it is also impermissible to attribute steps and functions recited in the claims of the '772 application to the instantly claimed invention in the absence of a basis found in the instant specification. Steps and functional limitations that are taught and claimed in the '772 application cannot be applied *a priori* to the instant claims without support or teaching from the instant application and/or claims. Accordingly, in view of the nonobvious differences between the invention claimed in the '772 application and the instantly claimed invention, it is respectfully requested that this rejection be withdrawn.

Claims 34-36, 38-48, 50, 52 and 55-67 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 50-52, 54-92 and 97-131 of copending application U.S. Serial No. 09/443,863 (hereinafter "the '863 application").

According to the Examiner, the conflicting claims are not identical, but are not considered to be patentably distinct from each other because the "claims in both applications are drawn to the same method of preparing the microparticles."

Applicants respectfully disagree with this rejection. First, the claims of the '863 application are not directed to a method of making fenofibrate microparticles, but rather are directed to a process of preparing a rapidly disintegrating solid dosage form comprising stabilized microparticles containing a water insoluble or poorly water soluble drug. The process claimed in the '863 application requires components and steps that function as specifically described to produce the claimed rapidly disintegrating solid dosage form. The claimed invention as supported by the teaching of the '863 application is distinct from and distinguished over the instant claims. The instant claims are clearly different from the '863 application's claims, which recite the use of rapidly

dispersible matrix-forming bulking and releasing agents, or combinations thereof, in amounts that allow for the specified functions of the rapidly disintegrating dosage form as recited in the claims of the '863 application.

The instant claims are not drawn to and are not obvious over the claimed process of the '863 application. The claims of the '863 application are directed to admixing a homogeneous aqueous suspension of microparticles comprising a water insoluble or a poorly water soluble drug and surface stabilizing agents, including at least one phospholipid, and one or more rapidly dispersible matrix forming bulking and/or releasing agents to produce a dried solid form of the suspension having the recited properties of non-aggregation and non-agglomeration, and further producing a solid that has stabilized drug particles dispersed and embedded throughout a support matrix formed by the one or more bulking and/or releasing agents, such that this support matrix disperses with a rapid disintegration time. The instant claims do not recite a solid support matrix in which drug particles are dispersed and embedded throughout. The steps, components and functionalities as claimed in the '863 application are distinct from the instantly claimed invention. The '863 application claims clearly describe a process that involves steps, components and functional results that are distinctive and non-obvious in view of the methods claimed in the instant application.

Second, the claims as a whole must be considered in making a determination of obviousness. In view of this, it is submitted that the claims of the '863 application, considered as a whole, contain steps that are patentably distinguished over the presently amended claims considered in their entirety. Based on the disclosure and teachings of the respective applications, it is submitted that it would not have been obvious for one having skill in the art to utilize the particular "additional steps" recited in the claims of the '863 application, which contain specified components and functions for producing a rapidly disintegrating dosage form of water insoluble or poorly water soluble drug-containing microparticles, to arrive at the presently claimed invention considered in its entirety. The inventions claimed in the instant application and in the '863 application are patentably distinct and are not obvious in view of each other.

Lastly, it is impermissible to invoke hindsight reconstruction to determine that the instantly claimed method is made obvious by the claims of the '863 application, which are drawn to a distinctly different process comprising similar, but also additional and distinguishing steps and components that function together in a nonobvious manner to achieve a nonobvious result as recited in the claims of the '863 application. It is respectfully submitted that it is also impermissible to attribute steps and functions recited in the claims of the '863 application to the instantly claimed invention in the absence of a basis in the instant specification. Steps and functional limitations that are taught and claimed in the '863 application cannot be applied *a priori* to the instant claims without support or teaching from the instant application and/or claims. Accordingly, in view of the nonobvious differences between the invention claimed in the '863 application and the instantly claimed invention, it is respectfully requested that this rejection be withdrawn.

Claims 34-36, 38-48, 50, 52 and 55-67 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 11-37 of copending application U.S. Serial No. 09/443,862 (hereinafter "the '862 application").

According to the Examiner, the conflicting claims are not identical, but are not considered to be patentably distinct from each other because the claims in both applications are drawn to the same method of preparing the microparticles.

To expedite prosecution of the application without acquiescing to the propriety of this rejection, a terminal disclaimer and the required fee are submitted herewith. Withdrawal of the rejection is thus respectfully requested.

CONCLUSION

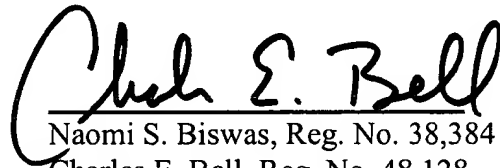
Applicant respectfully submits that this application is now in condition for allowance. An action progressing this application to issue is courteously urged.

Should any additional fees be deemed to be properly assessable in this application for the timely consideration of this Amendment and response, or during the pendency of this application, the Commissioner is hereby authorized to charge any such additional fee(s), or to credit any overpayment, to Deposit Account No. **50-0311**, Reference No. **28069-547-CIP2**.

Should any questions or issues arise concerning the application, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,

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